

alignment features including a first alignment indicia 356 and a second alignment indicia 358 on the rotatable portion of housing 360 and the non-rotatable portion of housing 362 respectively. In practice, to change inserter assembly 350 from a locked position (as shown, for example, in FIG. 59) to an unlocked position (as shown, for example, in FIG. 61) the rotatable portion of housing 360 is rotated, with respect to the non-rotatable portion of housing 362, in the direction indicated by the lock direction indicia 354, until the first alignment indicia 356 is aligned with the second alignment indicia 358. In some embodiments, the first alignment indicia 356 and second alignment indicia 358 may be different from the ones shown in, for example, FIGS. 59-60. In various embodiments, the alignment indicia 356, 368 may be any shape and/or size and or may be any feature on the housing portion 352, including, but not limited to, a marking, indent/emboss, painted feature, written feature, and/or raised feature. Any of the alignment indicia 356, 358 may be any one or more of these types of features, or any other such features to indicate to a user/caregiver that the inserter assembly 350 is in the locked or unlocked position.

[0118] Still referring also to FIGS. 59-71, a button assembly 360 (which may also be referred to as the rotatable portion of housing) includes ramps 368, 369. In the locked position, the ramps 368, 369 do not interact with any other features of the inserter assembly. The button assembly 360 also includes tab indents 402 which, in the locked position, receives sliding component tabs 370, 372. Thus, in the locked position, the sliding component tabs 370, 372 are inside the tab indents 402 and this prevents force exerted in a downward motion (i.e., in the direction towards the infusion set 398) on the button assembly 360 from moving the button assembly 360, thus, the button assembly 360 is in a locked position. Thus until and unless the button assembly 360 (or rotatable portion of housing 360) is rotated to the unlocked position, the button assembly 360 cannot actuate the inserter assembly 350. This may be beneficial/desirable for many reasons, including but not limited to, prevention of mis-initiation or unintentional initiation of the inserter assembly.

[0119] When the button assembly 360/rotatable portion of housing 360 is rotated with respect to the non-rotatable portion of housing 362, the ramps 368, 369 also rotate and the sliding component tabs 370, 372 are removed from the tab indents 402 and now interact/touch the ramps 368, 369. The first alignment indicia 356 and second alignment indicia 358 are aligned. In this position the button assembly 360 may be actuated and thus initiate the inserter assembly two-step sequence.

[0120] Referring now also to FIGS. 62-71, the inserter sequence is shown and described. To initiate the inserter assembly 350, a user or caregiver exerts force/pressure on the button assembly 360 in the downward direction (i.e. in the direction of the infusion set 398). The sliding component tabs 370, 372 maintain the sliding component 374 in the starting position. As the button assembly 360 advances downward, the ramps 368, 369 push the sliding component tabs 370, 372 out of the way of the sliding component 374. The sliding component spring 390 is released and the sliding component 374 is pushed downwards, i.e., towards the infusion set 398 (see FIGS. 63-65). The sliding component 374 moving downward also pushes the needle carrier 376 downward. The needle component 376 is connected to the introduction needle 394 and at this stage, the cannula 396 is

located around the introduction needle 394 forming a introduction needle/cannula assembly 392.

[0121] The needle carrier 376 and sliding component 374 continue moving downward (see FIGS. 66-67). This also pushes the insertion set 398 downward towards the user's skin 406. The sliding component 374 continues a downward path until the sliding component bottom tab 388 meets the slider stop 384 (see FIG. 69).

[0122] The needle carrier 376 continues a downward path even after the sliding component bottom tab 388 meets the slider stop 384. At that point the needle carrier spring fingers 380, 382 of the needle carrier 376 are pushed inward by the slider stop 384 and the needle carrier 376 continues downward and in following this path, the downward force of the needle carrier 376 injects the introduction needle/cannula assembly 392 into the user's skin 406 (see FIG. 68).

[0123] When the needle carrier 376 reaches the end of its travel path, the infusion set 398 is on the user's skin and the cannula 396 is inserted in the user. The needle carrier 376 is then released and the needle spring 378 forces the needle carrier 376 and the introduction needle 394, as the introduction needle 394 is attached to the needle carrier 376, upwards, towards the button assembly 360 (see FIG. 71). The upward movement of the needle carrier 376 continues until the spring fingers 380, 382 are caught on the sliding component top tab 386. At this point, the needle carrier 376 is locked into an end position and the introduction needle 394 is completely inside the housing portion 352. The infusion set 398 is attached to the user and the cannula 396, which is part of the infusion set, has been successfully inserted into the user.

[0124] Thus, the needle carrier 376 is slidably moveable from a starting position (FIG. 63) to an injection position (FIG. 68) and then to an ending position (FIG. 70). The button assembly/rotatable portion of housing/rotatable button assembly 360 rotates from a locked position to an unlocked position. By exerting downward force onto the rotatable button assembly 360, the rotatable button assembly 360 moves downward, which forces the sliding component 374 downward (through interaction between the ramps 368, 369 and the sliding component tabs 370, 372), and the needle carrier 376, which is attached to the introduction needle 394, downward towards the user's skin. Once the needle carrier 376 reaches the injection position, the spring fingers 380, 382 are pushed inward and the needle spring 378 pushes/forces the needle carrier 376 to move upward, towards the rotatable button assembly 360, until it stops at the ending position.

[0125] In various embodiments, the infusion set 398 includes an adhesive layer 404. In some embodiments, the adhesive may be covered by a liner, for example, an adhesive liner 366. In some embodiments, before putting the inserter assembly 350 against the skin, the user/caregiver removes the adhesive liner. In some embodiments, no adhesive liner is included.

[0126] The various bases, connectors, inserters, and parts thereof, may be formed from any materials including, but not limited to, medical-grade plastic materials. The various needles described herein may be formed from any medical-grade materials. The cannula and tubing may be formed from any medical-grade materials. In various embodiments, the insertion set includes a base, connector, tubing and a luer connection or other connector configured to connect to a fluid source.